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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,056	01/11/2001	Diane Pennica	GENENT.2827A2	1938

7590 06/30/2005

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,056	PENNICA ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,8-11,15,16,18-21 and 96-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,8-11,15,16,18-21, 96-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2 IDSs*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. Response filed 03/31/2005 is acknowledged. Claims 2-4,8-11,15,16,18-21, 96-106 are pending.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) to US serial Nos 60/228914 and 60/197089 is acknowledged in view of showing of support for the claimed subject matter provided in the provisional applications provided by applicant.

Claim Rejections - 35 USC § 112, first paragraph (written description)

3. Claims 96,99,100-106 are rejected under 35 U.S.C. 112, first paragraph (written description) as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons of record and further in view of the following.

A. Claims 96,99,100,101,105,106: Claims 96,99 are drawn to polynucleotides having at least 99% degree of identity with polynucleotide encoding a[ny] PRO10282 and having nine potential transmembrane domains identified on Fig. 9, and claim 106 is drawn to polynucleotides comprising DNA having at least 99% degree of identity with polynucleotide positions 49-2049 of SEQ ID No. 1. As described in the specification,

the polynucleotide SEQ ID No. 1 (polynucleotide positions 49-2049 of which encode protein SEQ ID No. 2) is overexpressed in cancer tissues and thus can be used for cancer diagnostics. Polynucleotide SEQ ID No. 1 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims as drawn to polynucleotides DNA having at least 99% degree of identity with polynucleotide positions 49-2049 of SEQ ID No. 1, do not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less then 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. Therefore, sequence similarity result in an unpredictable and therefore unreliable correspondence between the newly discovered sequence and a similar biomolecule of known function or expression. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Accordingly, the specification does not provide a written description of the polynucleotide as

claimed, and, consequently, of their complement. Note, that even though specification indicates that SEQ ID Nos. 2,5 contain open reading frame encoding protein SEQ ID NO:2 or 5, the claims are not drawn to polynucleotides encoding a particular protein. The specification provides insufficient written description to support the genus encompassed by the claim.

Response to arguments

With respect to claims 96,99, applicant argues that amendment of claim 96 to address specific locations of polypeptide's domains overcomes the rejection. Examiner agrees that the amendment clarifies location of domains. However, the claims are still directed to a genus of polynucleotides that have 99% identity to polypeptide SEQ ID No. 2., i.e., the genus which, as addressed in the rejection does not have sufficient description in the specification.

With respect to claim 106 applicant has not provided any arguments.

B. Claims 102, 103 are drawn to polynucleotides having at least 99% degree of identity with polynucleotide encoding a[ny] PRO10282 polypeptide, wherein the latter binds an[y] antibody raised against protein SEQ ID No. 2. There is no written description of epitopes of SEQ ID No. 2 recognizable by an antibody against protein SEQ ID No. 2; thus there is no description of genus of PRO10282 polypeptides that would bind an[y] antibody raised against protein SEQ ID No. 2. Note that PRO10282 peptides are defined in the specification merely as polypeptides having sequence similarity to murine Stra6 (see specification, p.1).

Response to arguments

Applicant argues that specification teaches method for preparing of antibodies binding to PRO10282 polypeptides. First, there is no description of preparing antibodies on pages 132-135 of specification indicated by applicant. Second, even if there was a description of preparing antibodies against a particular polypeptide of, e.g., SEQ ID No. 2, there is no written description of epitopes of SEQ ID No. 2 recognizable by an antibody against protein SEQ ID No. 2, and thus there is no description of genus of PRO10282 polypeptides that would bind an[y] antibody raised against protein SEQ ID No. 2. Note that PRO10282 peptides are defined in the specification merely as polypeptides having sequence similarity to murine Stra6 (see specification, p.1).

Examiner maintains that the specification provides insufficient written description to support the genus encompassed by the instant claims.

4. (New rejection) Claim 96 is rejected under 35 U.S.C. 112, first paragraph (written description) as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim, as amended, introduces new matter in that, first, it addresses an isolated nucleic acid which encodes particular domains of SEQ ID No. 2. The specification does describe nucleic acid which encodes said domains of SEQ ID No. 2 (i.e., nucleic acid of SEQ ID No. 1), but does not disclose that a genus of nucleic acids which are 99% or more identical to DNA molecule encoding SEQ ID No. 2 and which do encode all of the above domains.

Second, the amended claim 96 addresses a domain 512-531 of SEQ ID No. 2 which is not addressed in the specification, namely domain 512-531 (see Fig. 2 which lists domains of SEQ ID No. 2).

5. (New rejection) Claims 102,103 are rejected under 35 U.S.C. 112, first paragraph (written description) as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim, as amended, introduces new matter in that, it addresses isolated nucleic acid which encodes a polypeptide which binds to antibody raised against PRO10282 polypeptide comprising fragment 532-667 of SEQ ID No. 2. Although specification addresses said fragment as a surface fragment (Example 3), it does not teach antibody raised against PRO10282 polypeptide comprising fragment 532-667 of SEQ ID No. 2, and does not teach isolated nucleic acid which encodes a polypeptide which binds to such antibody.

Claim Rejections - 35 USC § 112, first paragraph (enablement)

6. Claims 9,10 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid SEQ ID NO:1, does not reasonably provide enablement for polynucleotides of at least 900 nucleotides that are hybridizable to nucleic acid SEQ ID No. 1.

As described in the specification, the polynucleotide SEQ ID No. 1 itself is overexpressed in cancer tissues and thus can be used for cancer diagnostics. No

information about overexpression of any other polynucleotides, e.g., shorter polynucleotides having certain degree of hybridization to the polynucleotide SEQ ID No. 1 is present in the specification. Consequently, with the insufficient guidance and working examples, one skilled in the art could not use the invention with as claimed without an undue amount of experimentation.

Response to arguments

Applicant argues that polynucleotide fragments, such as those encompassed by claims 9,10, can be used as hybridization probes. There is no showing that such polynucleotide fragments will specifically hybridize to polynucleotide SEQ ID No. 1 (which would have enabled their use as specific hybridization probes). As there is no showing of structure required for the claimed polynucleotide fragments to be capable of specifically recognizing polynucleotide SEQ ID No. 1, one would expect that they will hybridize to other unrelated molecules as well. Thus, for example, a probe of 900 nucleotides would hybridize to polynucleotide described in WO 9854963 (see sequence accession number AAV84436, Database GenEmbl previously addressed in the art rejection of record), which encodes secreted protein having no disclosed relationship to the over-expressed polynucleotide of SEQ ID No. 1. Note, further, that the claim language does not limit stringency of hybridization, and is therefore encompasses a genus of polypeptides which would be capable of non-specific binding to either polynucleotide SEQ ID No. 1 or any other polynucleotide.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 2-4,8-11,15,16,18-21, 96-106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Applications No.10/119480, 10/216159, 10/216160, 10/216162, 10/216163, 10/216164, 10/216165, 10/216166, 10/216167, 10/216168, 10/218849, 10/218930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the pending applications are directed to polynucleotide SEQ ID No. 79 and polypeptide SEQ ID No. 80, which are identical to instantly claimed polynucleotide SEQ ID No. 1 and polypeptide SEQ ID No. 2. Further, claims #4 in the cited applications are directed to polynucleotides having >80% identity to polynucleotides listed in Table 1, PTA-1181 (i.e. instant SEQ ID No. 1) in particular.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 9, 15-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/218631, 10/227884, 10/230338, 10/230631. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed

to polynucleotides having >80% identity to polynucleotides listed in Table 1, PTA-1181 (i.e. instant SEQ ID No. 1) in particular.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631